

## **REMARKS/ARGUMENTS**

Reconsideration of the present application, as amended, is respectfully requested.

Since the present amendment raises no new issues for consideration and, in any event, places the present application in better condition for consideration on appeal, it is respectfully requested that this amendment be entered under 37 CFR 1.116 in response to the last Office Action dated February 7, 2007, which made final rejections as to the pending claims.

### **A. STATUS OF THE CLAIMS**

As a result of the present amendment, claims 1, 5, 11-13, 15-16 and 18 are presented in the case for continued prosecution. Claims 1 and 16 as amended herein include  $\beta$ ig-h3 at a concentration of 300  $\mu$ g/ml - 600  $\mu$ g/ml in water-soluble chitosan. Support can be found, for example, at page 18, line 2-5 and claim 8 originally claimed. Claims 8, 14 and 17 are cancelled without prejudice. No new matter has been added.

### **B. SUMMARY OF THE CLAIMED INVENTION**

The present invention provides compositions for stimulating bone-formation and bone-consolidation. The compositions as amended herein include water-soluble chitosan and tripolyphosphate in which the water-soluble chitosan contains  $\beta$ ig-h3 at a concentration of 300  $\mu$ g/ml - 600  $\mu$ g/ml. The mixed ratio of the water-soluble chitosan and the tripolyphosphate is in a range of 20:80 ~ 80:20 weight %. The  $\beta$ ig-h3 stimulates bone-formation and bone-consolidation and therefore enhances the efficacy of the water-soluble chitosan and the tripolyphosphate. Thus, the compositions of the present invention allow advantageously a shortened bone-generation period after bone extension.

### **C. CLAIM REJECTIONS UNDER 35 U.S.C. §112, First Paragraph**

At page 5 of the Office Action, claims 1, 12 and 13 are rejected under 35 USC 112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner has taken the position that the recitation of  $\beta$ ig-h3 concentration of 100  $\mu$ g-1 mg/ml contained in water-soluble chitosan is not supported by the specification. In response, without admitting or denying the position of the Examiner and for the purpose of advancing the prosecution of the application, Applicants amended claim 1 to recite that  $\beta$ ig-h3 is contained in water-soluble

chitosan at a concentration of 300 µg/ml - 600 µg/ml. Support can be found, for example, at page 18, line 2-5 and claim 8 originally claimed. Considering the claim amendment herein, the rejection is negated. Accordingly, reconsideration and removal of the rejection is respectfully requested.

**D. CLAIM REJECTIONS UNDER 35 U.S.C. §102(a)**

At page 6 of the Office Action, the Examiner has rejected the subject matter of claims 1, 5, 8 and 11-15 under 35 USC 102(a) as allegedly anticipated by Kim et al. (Pastic and Reconstructive Surgery 2002 (May), 109(6), 1966-1977).

The Examiner is reminded that “Applicant’s disclosure of his or her own work within the year before the application filing date cannot be used against him or her... Where the applicant is one of the co-authors of a publication cited against his or her application, he or she may overcome the rejection by filing an affidavit or declaration ... under 37 CFR 1.132 establishing that the article is describing applicant’s own work. An affidavit or declaration by applicant alone indicating that applicant is the sole inventor and that the others were merely working under his or her direction is sufficient to remove the publication as a reference...” *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982); **MPEP 2132.01**; **MPEP 715.01(c)**; *In re Facius*, 408 F.2d 1396, 161 USPQ 294 (CCPA 1969).

In response, it is urged that the Examiner has not made a proper *prima facie* case of the rejection.

The present application was filed under 35 USC 371 claiming the benefit of priority from PCT/KR02/01837 filed on September 30, 2002. The reference relied upon by the Examiner was published in May 2002 within one year from the filing date of the priority application. Among the five-identified coauthors of the reference, In-San Kim and Byung Chae Cho are co-inventors/Applicants of the present invention. The reference describes the subject matter of Applicants’ own invention. The other three (3) coauthors, Jae Woo Park, Ick Chan Kwon and Bong Soo Baik, merely worked under the co-inventors’ direction and they are not inventors of the present invention. See the Declaration under 37 CFR 1.132 filed concurrently with this response.

Accordingly, it is urged that Kim et al. is not prior art. Reconsideration and removal of the rejection is thus proper and respectfully requested.

#### E. CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)

At pages 6-9 of the Office Action, claims 1, 5, 8 and 11-15 are rejected under 35 USC 103(a) as allegedly unpatentable over Kim et al. (J Korean Soc Plast Reconstr Surg 2001, 28(3), 223-232). The Examiner has alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the composition of Kim et al. to produce the present invention.

In *KSR Int'l v. Teleflex, Inc.*, 550 U.S. \_\_\_\_ (2007), the Supreme Court rejected the CAFC's "teaching, suggestion, or motivation" test (TSM test) for obviousness. The Court appears to affirm the broader conception of the TSM test in *DyStar Textilfaben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F. 3d 1356, 1367 (2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (2006). The broad test provides that common knowledge and common sense is considered or a motivation can be found implicitly to combine prior art references. Considering the decision in the KSR court and the flexible test mentioned in the opinion, it is urged that the Examiner has not alleged a proper *prima facie* case of obviousness. Reconsideration and removal of the rejection is therefore proper and earnestly requested.

Kim et al. relates to effects of each of BMP-4,  $\beta$ ig-h3 and chitosan on bone formation and consolidation after bone extension. In the reference, each of 0.5 ml of BMP-4, 0.5 ml of  $\beta$ ig-h3, and 0.5 ml of 5% chitosan solution was injected with 0.5 ml of 5% tripolyphosphate to an area of bone extended. Kim et al. teaches that the group treated with BMP-4 and tripolyphosphate showed new bone formation and consolidation most significantly among the three groups. The group treated with  $\beta$ ig-h3 and tripolyphosphate showed less effect compared to that of the group treated with BMP-4 and tripolyphosphate. Among the three groups, the group treated with chitosan and tripolyphosphate showed the least effect on bone formation and consolidation. Unlike the claimed combined solution which requires  $\beta$ ig-h3 at a concentration of 300  $\mu$ g/ml-600  $\mu$ g/ml in chitosan, Kim et al. teaches treating BMP-4,  $\beta$ ig-h3 or chitosan separately and individually for stimulating bone formation and consolidation. Kim et al. does **not** explicitly and/or implicitly show or teach a motivation to combine " $\beta$ ig-h3 and chitosan" to produce a combined solution of " $\beta$ ig-h3 at a concentration 300  $\mu$ g/ml-600  $\mu$ g/ml in chitosan" and treat the combined solution with tripolyphosphate after bone extension to stimulate bone formation and consolidation. The Examiner relied on the single reference which teaches treating BMP-4,  $\beta$ ig-

h3 or chitosan with tripolyphosphate individually. There is no explicit or implicit teaching of treating a combined solution of "Big-h3 and chitosan" with tripolyphosphate in Kim et al. It is therefore urged that the Examiner has not established a *prima facie* case of obviousness.

The Examiner takes the position that it would have been *prima facie* obvious to combine two compositions used for the same purpose to provide a third composition for the same purpose. However, it is respectfully urged that the claimed invention relates to the field of biotechnology. This field has been repeatedly determined by the U.S. Patent and Trademark Office to be unpredictable, relative to other art areas. Thus, it is respectfully submitted that there is no teaching, of record, that would have provided the ordinary artisan with a reasonable expectation of success in making such a combination. Based on the present record, on the day before Applicants' priority date, it is just as likely that the ordinary artisan would have expected that the claimed invention would have failed to produce useful results, ie, that the components would have failed to be operative in combination, or even would have resulted in negative results due to conflicting mechanisms of action. Thus, it is urged that the present invention represents a patentably distinct improvement on that which is described by Kim et al. If the Examiner has personal knowledge of the art that would remedy this clear deficiency in the record, he is respectfully invited to submit a declaration under 37 CFR 1.132, making this information of record.

For all of the above reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### **F. FEES**

This response is being filed within a shortened period for response. Thus, no further fee is believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

**G. CONCLUSION**

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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